

### **REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

#### **I. CLAIM STATUS & AMENDMENTS**

Claims 20 and 21 were pending in this application when last examined and stand rejected.

Claims 20 and 21 have been amended to include a structural limitation so that a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part to produce increased signal strength. Support can be found in the disclosure, for example, at page 3, line 21 to page 4, line 26, page 5, lines 6-12 and page 7, line 20 to page 8, line 6.

Therefore, no new matter has been added by this amendment.

#### **III. PRIOR ART REJECTIONS**

In item 1 on page 2 of the Advisory Action, claim 20 remains rejected under 35 U.S.C. § 102(e) as anticipated by Harrison (US 6,432,290).

In item 2 on page 2 of the Advisory Action, claim 21 remains rejected under 35 U.S.C. § 103(a) as obvious over Harrison in view of Eteshola (Sensors and Actuators B, vol. 72, pp. 129-133 (2001)) and Sato (Analytical Sciences, vol. 15, pp. 525-529 (1999)).

These rejections are respectfully traversed as applied to the amended claims. Since Harrison is the primary reference in each rejection, the rejections will be addressed together below.

In item 1 on page 2 of the Action, it was indicated that the 102(e) rejection of claim 20 over Harrison was maintained, because the Applicants are arguing structural differences not in the claims. It was indicated that claim 20 includes an "intended use limitation" (*i.e.*, the last "wherein" clause) that does not impart any structural difference on the claimed apparatus over the apparatus disclosed in the prior art.

Similarly, in item 2, it was further indicated that the 103(a) rejection over Harrison, Eteshola and Sato was been maintained on the basis that the claims do not require the beads to actually reach the detector as argued.

In reply, claims 20 and 21 have now been amended to include a structural limitation to perform the recited "intended use".

Specifically, amended claim 20 calls for an enzyme immunoassay chip comprising a micro channel, which comprises a reaction liquid leading-in flow passage part, a reaction flow passage part and a detection flow passage part, which are successively connected with each other on a substrate. The reaction flow passage part consists of an inlet part for bead-bodies with antibodies fixed thereon, a flow stopping part for stopping the flow of the bead-bodies through the reaction flow passage part and an area between the inlet part for the bead-bodies and the flow stopping part. The flow stopping part has a channel depth that is shallower than that of the reaction flow passage part to thereby stop the flow of bead-bodies through the reaction flow passage part. In the enzyme immunoassay chip of the amended claims, the reaction flow passage part and the detection flow passage part are arranged so that a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part to produce increased signal strength. Thus, enzyme immunoassay chip of the amended claims is structurally arranged to be operable so that a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part so as to produce increased signal strength.

Accordingly, amended claim 20 now includes a structural limitation that achieves the objective of having a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part to produce increased signal strength.

Similarly, amended claim 21, which is directed to a method of using the enzyme immunoassay chip, clarifies that the beads to actually reach the detection flow passage part.

It is again respectfully submitted that the combination of Harrison, Eteshola and Sato fails to disclose or suggest an enzyme immunoassay chip structurally arranged to be operable so that a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part so as to produce increased signal strength.

In fact, it is respectfully submitted that Harrison could not teach the specific structure and function of a reaction flow passage part which consists of a inlet part for bead-bodies with antibodies fixed thereon, a flow stopping part for the bead-bodies and an area between the inlet part for the bead-bodies and the flow stopping part, whereby the enzyme immunoassay chip is capable of producing an increased signal strength, because the reaction flow passage part and the detection flow passage part are arranged so that a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part to produce increased signal strength.

As noted in the last response, Harrison describes a micro-fluidic analysis system having at least one pair of weirs (Ex. 6, 7 in Figs. 1A, 1B and 2A) formed across a main channel and at least one side channel (Ex. 5 in Fig. 1A, 1B and 2A) that is connected with the main channel between the weirs, which provides a higher resistance than the main channel. In this system, the solvent flow (as described in Fig. 2A) passes mainly along a cover plate, and it is not combined with a liquid in chamber (4) between the weirs. Again, it is noted that this structure differs from that of the claimed enzyme immunoassay chip. When the solvent flow in Harrison is moving at a high enough speed to cause agitation in chamber (4) between the weirs, a large volume of liquid flows into the reservoir (3) against the resistance of said side channel (5).

Furthermore, the system in Harrison (as described in Fig. 9) has trapping zones (25, 30 and 35) and each trapping zone is connected to side channels (24, 26, 29, 31, 35 and 36).

However, as described in column 17, line 66 to column 18, line 8 of Harrison, the elution solvent is provided from an upper stream side at the weir (6e), and is delivered to exit channel (37) or collection (4) at down stream side of the weir (6f).

Accordingly, the system of Fig. 9 is similar to the system of Fig. 2, and only provides a little part of a concentrated protein digest to the stage of final analysis.

Therefore, in the micro-fluidic analysis system of Harrison, the majority of beads (12) in the chamber (4) do not contribute to the increase of signal strength, which contrasts with the present invention. Thus, the system in Harrison cannot achieve “the increased signal strength” as in the present invention, because the majority of elution of the fluorescent labeled reagent does not reach to detector (2) in Harrison. As such, Harrison describes a micro-fluidic analysis system, wherein the bead-bodies therein do not contribute to signal strength, because the majority of beads do not reach the detector as in the present invention. Again, this system contrasts with that of the present invention. The invention in Harrison only adds to the technical problem in the prior art, which was eventually solved by the present invention (i.e., to “obtain a signal strength sufficient for the measurement”).

Furthermore, in the micro-fluidic analysis system of Harrison, the beads (12) are added to the chamber (4) between at least one pair of weirs (6 and 7) by a side channel (5), which is connected with the chamber (4). In other words, the side channel (5), which is connected with the chamber (4), is indispensable, because it supplies beads to the chamber. Such structure is different from that of the present invention.

The secondary references of Eteshola and Sato fail to rectify this deficiency in Harrison. Specifically, Eteshola and Sato fail to provide a suggestion to improve upon the structure of the micro channel in Harrison to obtain a reaction flow passage part and a detection flow passage part, which are arranged so that a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part to produce increased signal strength.

Instead, Sato relates to a thermal-lens microscope to detect optical irradiation in a micro-fluidic channel. Eteshola relates to downstream detection of a fluorophore in a micro-fluidic device. As discussed above, neither reference provides a suggestion to modify the micro-fluidic device of Harrison to arrive at the claimed enzyme immunoassay chip, wherein a majority of

enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part to produce increased signal strength. These references fail to disclose or suggest any means for providing increased signal strength or passing a majority of enzyme reaction products beyond the weir in the micro-fluidic analysis system of Harrison.

Therefore, Harrison, and the combination of the secondary references of Eteshola, and Sato, fail to teach or suggest each and every element of the claimed invention.

In view of the above, the 102(e) anticipation rejection over Harrison and the 103(a) obviousness rejection over Harrison in view of Eteshola and Sato are untenable and should be withdrawn.

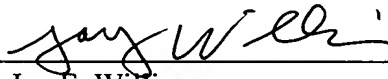
**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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